Exhibit L

***State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.*, Master Civil Action No. 01-12257-PBS, Subcategory Case No. 06-11337**

Exhibit to the December 21, 2009 Declaration of Christopher C. Palermo in Support of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc's. Opposition to Plaintiffs' Motion for Partial Summary Judgment

2/1.91

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Manufacturer, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a)"Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if

Benjamin Wu

cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b)"Base Consumer Price Index-Urban (CPI-U)"is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c)"Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d)"Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it

shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(g)"Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d)(1)-(3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(h)"Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(i)"Health Care Financing Administration (HCFA)" means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(j)"Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by HCFA as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by HCFA.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k)"Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l)"Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n)"Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the manufacturer to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o)"National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q)"New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r)"New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s)"Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t)"Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u)"Quarter" means calendar quarter unless otherwise specified.

(v)"Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w)"Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single-award contract.

(y)"Single-Award Contract Price" means a price established under a Single-Award Contract.

(z)"Single Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa)"States" means the 50 states and the District of Columbia.

(bb)"State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc)"Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd)"Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee)"Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the manufacturer sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with HCFA's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a)The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary

in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b)If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II(b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, HCFA shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify HCFA and for HCFA to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by HCFA will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an

initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Chief, Non-Institutional Payment Policy Branch
Office of Medicaid Policy, Medicaid Bureau
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to HCFA concerning data transfer and information systems issues are to be sent to:

Chief, Program Quality and Evaluation Branch
Office of Medicaid Management, Medicaid Bureau
Post Office Box 26686
Baltimore, MD. 21207-0486

The HCFA address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to HCFA at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) **Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.**

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate HCFA official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

Title: Deputy Director, Medicaid Bureau
Health Care Financing Administration
Department of Health and Human Services

Date: 2-11-91

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations , amendments or other changes to this rebate agreement.

By: _____

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

APPENDIX A

MEDICAID DRUG REBATE DATA ELEMENTS
DATA SUBMISSION FROM MANUFACTURERS TO HCFA

* Indicates that field is left blank for initial submission of baseline data.

** Indicates that these fields are zero-filled for Noninnovator Multiple Source Drugs

	Description	Size
	Labeler code, 1st segment of NDC	(05)
	Product Code, second segment of NDC	(04)
	Package Size code, third segment of NDC	(02)
	Period Covered, Calendar Quarter and Year	(03)
	Product FDA Registration Name	(63)
	Drug Category: Single Source, Innovator Multiple Source, or Noninnovator Multiple Source	(01)
	DESI Drug Indicator	(01)
	FDA Therapeutic Equivalence Explanation Code	(02)
	Unit Type: cc, ml, tablet, etc.	(03)
	Units per package size code	(10)
*	Average Manufacturer's Price	(11)
**	Baseline AMP	(11)
*/**	Best Price	(11)
	FDA Approval Date	(06)
	Date Drug Entered Market	(06)
	Drug Termination Date	(06)
	Drug Type (Rx or OTC) Indicator	(01)
	Correction Record Flag	(01)

Note: The Labeler Name is to be supplied in Enclosure B, the data systems information form that is to be completed and returned with the signed rebate agreement.

1

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 1 OF 4)
SUPPLEMENTAL DATA SHEET

00378
LABELER CODE (as assigned by FDA)

MYLAN PHARMACEUTICALS INC
LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT: Person to contact for legal issues concerning the rebate agreement.

ROGER L FOSTER
NAME OF CONTACT

304 (AREA) 599-2575 (PHONE NUMBER) -220 (EXT.)

MYLAN PHARMACEUTICALS INC
NAME OF CORPORATION

781
CHESTNUTRIDGE RD.

STREET ADDRESS

MORGANTOWN (CITY) WV (STATE) 26505 (ZIP CODE)

FINANCIAL CONTACT: Person responsible for financial aspects of rebate process.

FRANK DEGEORGE
NAME OF CONTACT

304 (AREA) 599-2595 (PHONE NUMBER) -238 (EXT.)

MYLAN PHARMACEUTICALS INC
NAME OF CORPORATION

781
CHESTNUTRIDGE RD

STREET ADDRESS

MORGANTOWN (CITY) WV (STATE) 26505 (ZIP CODE)

NOTE: THIS SHEET TO BE RETURNED WITH SIGNED REBATE AGREEMENT. IF MORE THAN ONE LABELER CODE ATTACH ONE SHEET FOR EACH LABELER CODE.

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 2 OF 4)
SUPPLEMENTAL DATA SHEET

00378
LABELER CODE (as assigned by FDA)

MYLAN PHARMACEUTICALS INC
LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT: Person responsible for sending and receiving data.

KIM ROSCHER
NAME OF CONTACT

AREA PHONE NUMBER EXT.

MYLAN PHARMACEUTICALS INC
NAME OF CORPORATION

781
WESTNUTRIDGE RD
STREET ADDRESS

MORGANTOWN WV 26505
CITY STATE ZIP CODE

NOTE: THIS SHEET TO BE RETURNED WITH SIGNED REBATE AGREEMENT. IF MORE THAN ONE LABELER CODE ATTACH ONE SHEET FOR EACH LABELER CODE.

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 3 OF 4)
SUPPLEMENTAL DATA SHEET

0 6 3 7 8
LABELER CODE (as assigned by FDA)

MYLAN PHARMACEUTICALS INC
LABELER NAME (Corporate name associated with labeler code)

FOR EACH STATE WITH WHOM THE LABELER HAS SIGNED AN EXISTING REBATE AGREEMENT:

STATE (postal code)	EFFECTIVE DATE (MMDDYY)	* ENDING DATE (MMDDYY)

NOTE: THIS SHEET TO BE RETURNED WITH SIGNED REBATE AGREEMENT. IF MORE THAN ONE LABELER CODE ATTACH ONE SHEET FOR EACH LABELER CODE.

IF THERE ARE MORE THAN 20 EXISTING AGREEMENTS PLEASE MAKE COPIES OF THIS PAGE.

* Date on which initial term of agreement occurs.

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 4 OF 4)
SUPPLEMENTAL DATA SHEET

00378
LABELER CODE (as assigned by FDA)

MYLAN PHARMACEUTICALS INC
LABELER NAME (Corporate name associated with labeler code)

PLEASE INDICATE YOUR MEDIA PREFERENCE WHICH YOU INTEND TO USE FOR TRANSMITTING DATA IDENTIFIED IN APPENDIX A OF THE REBATE AGREEMENT TO THE HEALTH CARE FINANCING ADMINISTRATION. THE INSTRUCTIONS, TECHNICAL SPECIFICATIONS AND MATERIALS APPROPRIATE TO THE OPTION SPECIFIED WILL BE MAILED TO YOU UPON RECEIPT OF YOUR AGREEMENT.

☑ OPTION 1 - **TELECOMMUNICATIONS**
Transmit data through telecommunications. Records formats are attached. Upon election of this option, HCFA will mail additional instructions, including the "Dial In" number of the HCFA electronic mailbox.
(See next pages for Telecommunications format.)

☐ OPTION 2 - **3 1/2" HD diskette**
For PC systems supporting MS/DOS 4.0 or higher. Upon election of this option, a preprogrammed diskette will be mailed to you, along with instructions.

☐ OPTION 3 - **PAPER**
For manufacturers with five or fewer drug products. The form for submitting data is attached.
(See next pages Paper Reporting Format)

NOTE: THIS SHEET TO BE RETURNED WITH SIGNED REBATE AGREEMENT. IF MORE THAN ONE LABELER CODE ATTACH ONE SHEET FOR EACH LABELER CODE.

DATE: M M/D D/Y Y

PAGE: OF

PAPER REPORTING FORMAT

MEDICAID DRUG REBATE AGREEMENT

QUARTERLY REPORT FOR QUARTER CALENDAR YEAR

FDA ASSIGNED LABELER CODE

PRODUCT CODE | PACKAGE SIZE CD | DRUG CAT. | THERA. EQ.CD. | DESI IND. | AVERAGE MFG. PRICE | BEST PRICE | DATE ENTERED MARKET

BASELINE AMP. | TERMINATION DATE | CORRECTION FLAG | UNIT TYPE | UNITS PER PACKAGE SIZE | FDA APPROVAL DATE

PRODUCT NAME | DRUG TYPE

PRODUCT CODE | PACKAGE SIZE CD | DRUG CAT. | THERA. RATING | DESI IND. | AVERAGE MFG. PRICE | BEST PRICE | DATE ENTERED MARKET

BASELINE AMP. | TERMINATION DATE | TERM. REASON | CORRECTION FLAG | UNIT TYPE | PACKAGE SIZE | FDA APPROVAL DATE

PRODUCT NAME | DRUG TYPE

PRODUCT CODE | PACKAGE SIZE CD | DRUG CAT. | THERA. RATING | DESI IND. | AVERAGE MFG. PRICE | BEST PRICE | DATE ENTERED MARKET

BASELINE AMP. | TERMINATION DATE | TERM. REASON | CORRECTION FLAG | UNIT TYPE | PACKAGE SIZE | FDA APPROVAL DATE

PRODUCT NAME | DRUG TYPE

NYMylan03061973

HCFA RECORD SPECIFICATION
MFR PRICING INFORMATION
TELECOMMUNICATIONS FORMAT

Record # 1

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "1"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Period Covered	3	13 - 15	QYY
Drug Category	1	16 - 16	See Data Element Definitions
FDA Thera. EQ. CD.	2	17 - 18	See Data Element Definitions
DESI Indicator	1	19 - 19	See Data Element Definitions
Drug Type Indicator	1	20 - 20	See Data Element Definitions
* Average Mfg Price	11	21 - 31	99999V999999
*/** Best Price	11	32 - 42	99999V999999
** Baseline AMP	11	43 - 53	99999V999999
Termination Date	6	54 - 59	MMDDYY
Correction Flag	1	60 - 60	See Data Element Definitions
Filler	20	61 - 80	

* Zero filled and not used for Initial Submission

** Only for Single Source and Innovator Multiple Source Drugs, otherwise zero filled

HCFA RECORD SPECIFICATION
MFR PRICING INFORMATION
TELECOMMUNICATIONS FORMAT

Record # 2

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "2"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Unit Type	3	13 - 15	See Data Element Definitions
Units Per Pkg Size	10	16 - 25	9999999V999
FDA Approval Date	6	26 - 31	MMDDYY
Date Entered Market	6	32 - 37	MMDDYY New Item Only
Filler	43	38 - 80	

Record # 3

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "3"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Product Name	63	13 - 75	FDA Registration Name
Filler	5	76 - 80	

ENCLOSURE C
MANUFACTURER DATA DEFINITIONS

****

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 digit field, right-justified and 0-filled for 4-digit labeler codes

****

DATA ELEMENT NAME: Product Code

DATA DEFINITION: Second segment of National Drug Code.

SPECIFICATIONS: Numeric values only, 4 digit field, right justified, zero filled

****

DATA ELEMENT NAME: Package Size Code

DATA DEFINITION: Third segment of National Drug Code.

SPECIFICATIONS: Numeric values only, 2 digit field right justified, zero filled

****

****

DATA ELEMENT NAME: Period Covered

DATA DEFINITION: Calendar quarter and year covered by data submission.

SPECIFICATIONS: Numeric 3-digit field, QYY

Valid Values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid Values for YY: last two digits of calendar year covered

For Baseline Data Submission, indicate third quarter of 1990 as 390.

****

DATA ELEMENT NAME: Product Registration Name

DATA DEFINITION: Product name as it appears on FDA registration form.

SPECIFICATIONS: Alpha-numeric values, 63 characters, left justified

****

DATA ELEMENT NAME: Drug Category

DATA DEFINITION: Classification of drug for purposes of rebate calculations.

SPECIFICATIONS: Alpha-numeric values, 1 character

Valid Values:
N = Non-innovator Multiple source
S = Single Source
I = Innovator Multiple Source

****

****

DATA ELEMENT NAME: DESI Drug Indicator

DATA DEFINITION: A DESI (Drug Efficacy Study Implementation) drug is any drug that lacks substantial evidence of effectiveness and is subject by the FDA to a Notice of Opportunity for Hearing (NOH). This includes drugs which are identical, related or similar to DESI drugs.

SPECIFICATIONS: Numeric value, 1 digit

Valid Values: 0 = not DESI drug
1 = DESI drug

****

DATA ELEMENT NAME: Therapeutic Equivalence Explanation Code

DATA DEFINITION: The classification as contained in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made.

SPECIFICATIONS: Alpha-numeric values, 2 character field

Valid Values:
AA
AB
AN
AO
AP
AT
BC
BD
BE
BN
BP
BR
BS
BT
BX
NR - Not rated

****

****

DATA ELEMENT NAME: Unit Type

DATA DEFINITION: Basic measurement that represents the smallest unit by which the drug can be measured. The rebate amount will be calculated per unit.

Example: For drugs that are dispensed in capsules or tablets, the Unit Type would be a capsule or tablet. The rebate amount would be calculated per capsule or tablet. For liquids, the Unit Type would be a milliliter. The rebate amount would be calculated per milliliter.

SPECIFICATIONS: Alpha-numeric values, 3 character field, left justified

Valid Values:

CAP = Capsule
CC = Cubic Centimeter
TAB = Tablet
GM = Gram
MCI = Millicurie
MG = Milligram
ML = Milliliter
SQC = Square Centimeter
UCI = Microcurie
UGM = Microgram
UM = Micromolar

****

****

DATA ELEMENT NAME: Units Per Package Size Code

DATA DEFINITION: Total number of units, as defined in the Unit Type field, in the package represented by the package size code, or the third segment of the NDC code.

Example 1: For a drug dispensed in a package size of 100 cc, the unit type would be a cc, and the units per package size would be 100.

Example 2: For a 17 microgram inhaler, the unit type would be a microgram and the units per package size would be 17.

SPECIFICATIONS: Numeric values, 10 digit field: 7 whole numbers and 3 decimal places

****

DATA ELEMENT NAME: AMP (Average Manufacturer's Price)

DATA DEFINITION: The Average Manufacturer's Price per unit per product code only for the period covered. If a drug is distributed in 3 package sizes, there will still be only one AMP for the product, which will be the same for all package sizes.

SPECIFICATIONS: Numeric values, 11 digit field: five whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

****

****

DATA ELEMENT NAME: Baseline AMP (Average Manufacturer's Price).

NOTE: This is only required for Single Source and Innovator Multiple Source drugs, in initial submission, and for drugs approved by the FDA after 10/01/90.

DATA DEFINITION: The Average Manufacturer's Price per unit per product code only for the quarter ending September 30, 1990. If a drug is distributed in 3 package sizes, there will still be only one AMP for the product, which will be the same for all package sizes.

SPECIFICATIONS: Numeric values, 11 digit field: five whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

Zero fill for Non-innovator Multiple Source drugs.

****

DATA ELEMENT NAME: Best Price

NOTE: This is only required for Single Source and Innovator Multiple Source drugs, in initial submission, and for drugs approved by the FDA after 10/01/90.

DATA DEFINITION: The lowest price available from the labeler to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices of any agency of the Federal Government).

SPECIFICATIONS: Numeric values, 11 digit field: five whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

Zero fill for Non-innovator Multiple Source drugs.

****

DATA ELEMENT NAME: FDA Approval Date

DATA DEFINITION: Date of FDA Approval of drug, if approved after 06/30/90, otherwise, zero fill this field.

SPECIFICATIONS: Numeric values, 6 digit field

MMDDYY

****

DATA ELEMENT NAME: Date Drug Entered Market

DATA DEFINITION: First day of the first month that the drug was marketed for the entire month.

Example: If a drug is first sold on February 15, the first day of the first full month of marketing is March 1.

SPECIFICATIONS: Numeric values, 6 digit field

MMDDYY

****

DATA ELEMENT NAME: Drug Termination Date

DATA DEFINITION: Date drug withdrawn from market or no longer distributed by labeler.

SPECIFICATIONS: Numeric values, 6 digit field

MMDDYY

****

****

DATA ELEMENT NAME: Drug Type Indicator

DATA DEFINITION: Indicator to show whether this drug product can be acquired only by prescription or can be acquired Over-The-Counter (OTC).

1 = Rx
2 = OTC

****

DATA ELEMENT NAME: Correction Record Flag

DATA DEFINITION: Indicator that this record corrects and replaces a record already submitted for the initial submission.

SPECIFICATIONS: Numeric one-digit field.

Valid Values: 0 = Original Record
1 = Correction Record

ENCLOSURE D

MEDICAID DRUG REBATE DATA ELEMENTS
RECORD FROM HCFA TO STATE AGENCIES QUARTERLY

Description	Size
Period covered, Calendar Quarter and Year	(03)
Labeler Code, 1st segment of NDC	(05)
Product Code, second segment of NDC	(04)
Package Size Code, third segment of NDC	(02)
Product FDA Registration Name (abbr.)	(10)
Drug Category: Single Source, Innovator Multiple Source or Non-innovator Multiple Source	(01)
DESI Drug Indicator	(01)
FDA Therapeutic Equivalence Explanation Code	(02)
Unit Type: cc, ml, tablet, etc.	(03)
Units Per Package Size Code	(10)
Rebate Amount Per Unit	(11)
FDA Approval Date	(06)
Date Drug Entered Market	(06)
Drug Termination Date	(06)
Drug Type (Rx or OTC)	(01)
Correction Record Flag	(01)

ENCLOSURE E

MEDICAID DRUG REBATE DATA ELEMENTS
RECORD FROM STATE AGENCIES TO HCFA AND MANUFACTURERS QUARTERLY

Description	Size
State Code (Post Office abbr.)	(02)
Period Covered, Calendar Quarter and Year	(03)
Labeler Code, 1st segment of NDC	(05)
Product Code, second segment of NDC	(04)
Package Size Code, third segment of NDC	(02)
Product FDA Registration Name (abbr.)	(10)
Rebate Amount Per Unit	(11)
Total Units Reimbursed (per NDC)	(12)
Total Rebate Amount Claimed (per NDC)	(09)
Number of Prescriptions Reimbursed (per NDC)	(06)
Total Reimbursement Amount (per NDC)	(10)
Correction Record Flag	(01)

****

DATA ELEMENT NAME: State Code

DATA DEFINITION: Two character Post Office abbreviation for State.

SPECIFICATIONS: Alpha-numeric, 2 positions.

****

DATA ELEMENT NAME: Period Covered

DATA DEFINITION: Calendar quarter and year covered by data submission.

SPECIFICATIONS: Numeric 3 digit field, QYY

Valid Values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid Values for YY: last two digits of calendar year covered

****

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 digit field, right-justified and zero filled for 4 digit labeler codes

****

****

DATA ELEMENT NAME: Product Code

DATA DEFINITION: Second segment of National Drug Code.

SPECIFICATIONS: Numeric values only, 4 digit field, right justified, zero filled

****

DATA ELEMENT NAME: Package Size Code

DATA DEFINITION: Third segment of National Drug Code.

SPECIFICATIONS: Numeric values only, 2 digit field right justified, zero filled

****

DATA ELEMENT NAME: Product FDA Registration Name (abbr.)

DATA DEFINITION: First 10 characters of Product FDA Registration Name.

SPECIFICATIONS: Alpha-numeric values, 10 positions

****

DATA ELEMENT: Rebate Amount Per Unit

DATA DEFINITION: HCFA-calculated amount per unit type.

SPECIFICATIONS: Numeric values, 11 digits: 5 whole numbers and 6 decimals. Calculate to 7 decimals and round to 6. If not available, this field will appear as all zeroes.

****

****

DATA ELEMENT NAME: Total Units Reimbursed

DATA DEFINITION: The total number of units per NDC, of the drug reimbursed by the State during the period covered. Drugs dispensed before January 1, 1991, will not be included.

SPECIFICATIONS: Numeric values, 12 digits: 9 whole numbers and three decimals.

****

DATA ELEMENT NAME: Total Rebate Amount Claimed

DATA DEFINITION: The total rebate amount per NDC that the State Agency claims it is owed by the labeler for the quarter covered. It is calculated by multiplying the Total Units Reimbursed by the Rebate Amount per Unit.

SPECIFICATIONS: Numeric values, 9 digits: 7 whole numbers and 2 decimal places

****

DATA ELEMENT NAME: Number of Prescriptions

DATA DEFINITION: Number of prescriptions reimbursed per NDC during the quarter.

SPECIFICATIONS: Numeric values, 6 digits, whole numbers only

****